

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

UNITED THERAPEUTICS)
CORPORATION,)
Plaintiff,)
v.) C.A. No. 23-975-RGA
LIQUIDIA TECHNOLOGIES, INC.,)
Defendant.)

**LIQUIDIA'S BRIEF IN SUPPORT OF PARTIAL MOTION TO DISMISS
COUNTS I AND II OF PLAINTIFF'S FIRST AMENDED COMPLAINT**

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Pursuant to Federal Rule of Civil Procedure 12(b)(6), Liquidia Technologies, Inc. (“Liquidia”) moves to dismiss Counts I and II of United Therapeutics Corporation’s (“UTC”) First Amended Complaint directed to allegations of infringement of U.S. Patent No. 10,716,793 (the “’793 patent”), as well as any paragraphs and relief requested associated with Counts I and II in light of the Federal Circuit’s December 20, 2023 decision affirming the invalidity of the ’793 patent. (Ex. 1 (Fed. Cir. ’793 Patent Decision).)

I. NATURE AND STAGE OF THE PROCEEDING

UTC sued Liquidia on September 5, 2023, alleging infringement of the ’793 patent. (See D.I. 1.) On November 30, 2023, UTC filed its First Amended Complaint, again alleging infringement of the ’793 patent, but also adding allegations of infringement of recently issued U.S. Patent No. 11,826,327 (the “’327 patent”). (See D.I. 8.) On December 8, 2023, the parties filed a stipulation to extend the time for Liquidia to respond to the First Amended Complaint until January 16, 2024 (D.I. 10), which the Court granted on December 8, 2023. Subsequently, on December 20, 2023, the United States Court of Appeals for the Federal Circuit issued a decision (the “’793 Patent Federal Circuit Decision”), affirming the United States Patent Trial and Appeal Board’s Final Written Decision (“FWD”) rendering all claims of the ’793 patent invalid as obvious. (Ex. 1 (Fed. Cir. ’793 Patent Decision).)

II. SUMMARY OF THE ARGUMENT

UTC’s allegations of infringement of the ’793 patent are barred under the doctrine of collateral estoppel based on the ’793 Patent Federal Circuit Decision. The ’793 patent is invalid and that decision has immediate collateral estoppel effect since the December 20, 2023 ’793 Patent Federal Circuit Decision. Under controlling precedent, Counts I and II of the First Amended Complaint, directed to the ’793 patent, must be dismissed. *See XY, LLC v. Trans Ova Genetics, L.C.*, 890 F.3d 1282, 1294 (Fed. Cir. 2018).

III. STATEMENT OF FACTS

Liquidia filed a New Drug Application (“NDA”) No. 213005 under § 505(b)(2) of the Federal Food, Drug and Cosmetic Act and subsequently amended that NDA to include a new indication. (D.I. 8 at ¶¶ 3, 18.) In view of Liquidia’s amendment to its NDA, UTC sued Liquidia on September 5, 2023 under the Hatch-Waxman Act, alleging infringement of the ’793 patent. (See D.I. 1 at ¶ 1.) On November 30, 2023, UTC filed its First Amended Complaint, again alleging infringement of the ’793 patent in Counts I and II, but also adding allegations of infringement of recently issued U.S. Patent No. 11,826,327 (the “’327 patent”). (See D.I. 8.)

Prior to UTC’s assertion of the ’793 patent in this action, Liquidia submitted an *Inter Partes* review (“IPR”) petition regarding the ’793 patent on January 7, 2021. The Patent Trial and Appeal Board (“PTAB”) instituted review and issued a FWD on July 19, 2022. (Ex. 2 (’793 FWD).) In its FWD, the PTAB found claims 1-8 of the ’793 patent unpatentable as obvious over the prior art under 35 U.S.C. § 103. (*Id.*, 46.) UTC filed a request for rehearing by the PTO’s Precedential Opinion Panel, which was denied on October 26, 2022, but with directions for the PTAB panel to further assess the public availability prior art status of two abstracts. (Ex. 3 (Order to Assess Public Availability).) On February 2, 2023, the PTAB panel denied UTC’s request for rehearing and confirmed that the abstracts were publicly accessible prior art before the ’793 patent’s priority date, although modifying the grounds for that holding. (Ex. 4 (Denial of Rehearing Request, 7–13).) UTC appealed the PTAB panel’s FWD to the Federal Circuit, which affirmed the invalidity ruling in a non-precedential opinion issued on December 20, 2023 (“the ’793 Patent Federal Circuit Decision”). (Ex. 1 (Fed. Cir. ’793 Patent Decision).) UTC has indicated it intends to seek panel and en banc rehearing of the non-precedential ’793 Patent Federal Circuit Decision, but it has not yet filed such a request.

IV. ARGUMENT

A. Applicable Legal Standards.

Federal Rule of Civil Procedure 12(b)(6) requires dismissal of a complaint when that complaint fails to state a claim upon which relief can be granted. *See Fed. R. Civ. P. 12(b)(6); Fed. R. Civ. P. 8(a)(2)*. A complaint must be dismissed under Rule 12(b)(6) if it fails to plead “enough facts to state a claim to relief that is plausible on its face.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). “A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). If the pleaded facts do not permit this Court to draw such a reasonable inference, the complainant is not entitled to relief. *See Int'l Bus. Machs. Corp. v. Rakuten, Inc.*, No. 21-461-GBW, 2022 WL 17848779, at *7–9 (D. Del. Dec. 22, 2022) (granting motion to dismiss infringement claims based on collateral estoppel because the patents were invalidated in a previous proceeding).

B. Dismissal of Counts I and II Is Warranted Under Rule 12(b)(6) Because the Federal Circuit Has Determined that the '793 Patent Claims in this Case Are Invalid.

Count I of the First Amended Complaint alleges Liquidia’s Proposed § 505(b)(2) Product infringes claims of the '793 patent under 35 U.S.C. § 271(e). (D.I. 8 at ¶¶ 30-37.) Count II alleges infringement of the '793 patent under 35 U.S.C. §§ 271(a)-(c). (*Id.* at ¶¶ 38-51.) But it is well-settled that an accused defendant cannot be liable for infringement of an invalid claim. *See Commil USA, LLC v. Cisco Sys., Inc.*, 575 U.S. 632, 644 (2015) (“To be sure, if at the end of the day, an act that would have been an infringement or an inducement to infringe pertains to a patent that is shown to be invalid, there is no patent to be infringed.”); *Translogic Tech., Inc. v. Hitachi, Ltd.*, 250 F. App’x 998 (Fed. Cir. 2007) (vacating the district court’s infringement decision and remanding for dismissal in light of the Federal Circuit’s decision affirming invalidity of the

patent); *U.S. Ethernet Innovations, LLC v. Tex. Instruments Inc.*, 645 F. App'x 1026, 1028-30 (Fed. Cir. 2016); *IPPV Enters., LLC v. Echostar Commc'ns, Corp.*, 191 F. Supp. 2d 530, 562 (D. Del. 2002); *United Therapeutics Corp. v. Liquidia Techs., Inc.*, 624 F. Supp. 3d 436, 449 n.7 (D. Del. 2022) (quoting *Commil*, 575 U.S. at 644); *Merck Sharp & Dohme Corp. v. Hospira Inc.*, 221 F. Supp. 3d 497, 521 n.21 (D. Del. 2016) (“Since I ultimately conclude that the ’150 patent is invalid as obvious, there is ultimately no infringement.”) Here, there can be no dispute that the ’793 patent has been shown to be invalid, and finally so. As such, UTC’s factual allegations of infringement of the ’793 patent in Counts I and II are not plausible on their face because of the ’793 patent’s invalid status.

As discussed above, the Federal Circuit finally adjudicated the validity of the ’793 patent, affirming the PTAB’s FWD that all claims of the ’793 patent are invalid as obvious. (Ex. 1 (Fed. Cir. ’793 Patent Decision).) Under *XY, LLC v. Trans Ova Genetics, L.C.*, the ’793 Patent Federal Circuit Decision “has an **immediate** issue-preclusive effect on any pending or co-pending actions involving the patent[,]” like the instant action. 890 F.3d at 1294 (emphasis added); *see also U.S. Ethernet*, 645 F. App'x at 1029–30 (“[A] patentee, having been afforded the opportunity to exhaust his remedy of appeal from a holding of invalidity, has had his ‘day in court’ and should not be allowed to harass others on the basis of an invalid claim.”) (*citing Blonder-Tongue Lab'ys, Inc. v. Univ. of Ill. Found.*, 402 U.S. 313, 339 (1971)).

Under Third Circuit law, collateral estoppel applies when “(1) the identical issue [was] previously adjudicated; (2) the issue [was] actually litigated; (3) the previous determination of the issue [was] necessary to the decision; and (4) the party being precluded from relitigating the issue [was] fully represented in the prior action.” *Int'l Bus. Machs.*, 2022 WL 17848779, at *4 (quoting *Stone v. Johnson*, 608 F. App'x 126, 127 (3d Cir. 2015)). Here, the four factor test has been met.

First, the '793 patent claims are invalid as obvious over the prior art. (*See* Ex. 2 ('793 FWD).) Second, this identical issue was previously litigated before the PTAB, satisfying factors 1 and 2. (*Id.*) Third, the issue of obviousness of the '793 patent claims was decided on the merits by the PTAB and affirmed by the Federal Circuit. (*See* Exs. 1, 2.) Finally, UTC was adequately represented by multiple law firms and counsel and had a full and fair chance to litigate the issue of the validity of the '793 patent claims, both before the PTAB and Federal Circuit. (*Id.*)

There is no room for factual or legal debate that because the '793 patent is invalid, Liquidia cannot be liable for infringement of that patent. *See XY*, 890 F.3d at 1294; *Commil*, 575 U.S. at 644. *XY*, is on-point with the facts presented here. In *XY*, the Federal Circuit affirmed the PTAB's determination of patent invalidity in a separate appeal. *XY*, 890 F.3d at 1294. Based on that separate decision, the Federal Circuit held that its affirmance "has an immediate issue-preclusive effect on any *pending or co-pending* actions involving the patent." *Id.* (emphasis added). Consequently, the Federal Circuit dismissed as moot, Trans Ova's co-pending appeal on the invalidity of the asserted patents. *Id.* at 1294–95. Here, like in *XY*, the '793 Patent Federal Circuit Decision has immediate collateral estoppel effect on this pending action involving the same '793 patent, warranting dismissal of Counts I and II. Indeed, UTC recognized the immediate collateral estoppel effect the '793 Patent Federal Circuit Decision has on co-pending actions involving the '793 patent. In letter briefing before this Court on the '793 patent citing *XY*, UTC acknowledged that a Federal Circuit decision affirming a PTAB decision on invalidity of the '793 patent has "immediate issue-preclusive effect." *United Therapeutics Corp. v. Liquidia Techs., Inc.*, No. 20-cv-755-RGA-JLH, D.I. 428 at 1 (Ex. 5). UTC cannot now argue otherwise.

That UTC may seek rehearing does not negate the immediate preclusive effect the '793 Patent Federal Circuit Decision has on this action and does not warrant denial of Liquidia's

requested relief. In *XY*, the Federal Circuit dismissed a co-pending appeal on the same day it issued its affirmance of the PTAB’s decision on that same patent—it did not wait for any decision on rehearing. 890 F.3d at 1294. The same rationale applies here—the potential pendency of a rehearing request does not diminish either the finality or the binding effect of the ’793 Patent Federal Circuit Decision. And for this same reason, claim cancellation under 35 U.S.C. § 318(b) is not required to grant the relief Liquidia requests because collateral estoppel applies now. In the unlikely event rehearing on a non-precedential decision is granted and the ’793 Patent Federal Circuit Decision is reversed or remanded, UTC can re-file its action. But unless and until then, controlling precedent warrants dismissal of Counts I and II of the First Amended Complaint.

V. CONCLUSION

For the foregoing reasons, Liquidia respectfully requests that the Court grant the relief requested and dismiss Counts I and II of the First Amended Complaint as well as any paragraphs and requests for relief associated with Counts I and II.

Respectfully submitted,

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